1619

PTO/SB/21 (03-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



# TRANSMITTAL FORM

*(to be used for all correspondence after initial filing)*

| | |
|---|---|
| Application Number | 10/057,323 |
| Filing Date | 01/25/2002 |
| First Named Inventor | Harry R. Davis, et al. |
| Art Unit | 1619 |
| Examiner Name | To Be Assigned |
| Attorney Docket Number | CV01489K |

Total Number of Pages in This Submission: 5

## ENCLOSURES (Check all that apply)

- [ ] Fee Transmittal Form
- [ ] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [x] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [x] Petition
- [ ] Petition to Convert to a Provisional Application
- [x] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s)

Remarks

- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) (please Identify below):

Form PTO-1449 (1 pg. in dup.)

References (13); Post Card

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | |
|---|---|
| Firm or Individual | Ann Marie Cannoni, Reg. No. 35,972 |
| Signature | |
| Date | April 29, 2003 |

## CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: April 29, 2003

| | | | |
|---|---|---|---|
| Typed or printed | Ann Marie Cannoni | | |
| Signature | | Date | April 29, 2003 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:
Harry R. Davis et al

For Patent For:
Combinations of Peroxisome Proliferator-Activated Receptor (PPAR) Activator(s) and Sterol Absorption Inhibitor(s) and Treatments for Vascular Indications

Examiner: To Be Assigned

Art Unit: 1619

Serial No.: 10/057,323

Filing Date: January 25, 2002

Schering-Plough Corporation
Kenilworth, New Jersey 07033-0530

Assistant Commissioner for Patents
Washington, D.C. 20231

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

Applicants respectfully request that the following be considered and made of record, as well as the documents listed on the accompanying PTO Form 1449.

A research study was initiated on April 17, 1997 in the United States in which patients were administered capsules of the formulations of Exhibits A, B or C. Copies of the formulation Exhibits A, B and C and the informed consent form for the study (Exhibit 1) are submitted herewith for the Examiner's consideration.

A research study was initiated on October 21, 1997 in the United States in which patients were administered tablets of the formulations of Exhibits D or E or capsules of formulation of Exhibit C. Copies of the formulation Exhibits C, D and E and the informed consent for the study (Exhibit 2) are submitted herewith for the Examiner's consideration.

A research study was initiated on November 5, 1998 in the United States in which patients were administered tablets of formulations of Exhibits D, F, G or H. Copies of the formulation Exhibits D, F, G and H and the informed consent for the study (Exhibit 3) are submitted herewith for the Examiner's consideration.

A research study was initiated on April 20, 1999 in the United States in which patients were administered tablets of the formulation of Exhibit D, optionally in coadministration with digoxin. Copies of the formulation Exhibit D and the informed consent for the study (Exhibit 4) are submitted herewith for the Examiner's consideration.

A research study was initiated on August 27, 1999 in the United States in which patients were administered tablets of the formulation of Exhibit D optionally in coadministration with Gemfibrozil 600mg tablets. Copies of the formulation Exhibit D and the informed consent for the study (Exhibit 5) are submitted herewith for the Examiner's consideration.

In the Informed Consents accompanying the above research studies, Schering's active pharmaceutical ingredient, i.e., ezetimibe, was identified as "SCH 58235" and as an "experimental drug which inhibits the absorption of cholesterol". It was not identified by its chemical name, generic name or by its chemical formula.

It is our belief that these studies do not constitute prior public uses. Nevertheless, this information is being disclosed in accordance with 37 C.F.R. Section 1.56 out of an abundance of caution.

The Commissioner is authorized to charge Deposit Account No. 19-0365 for any additional fees deemed necessary for consideration and entry of this Information Disclosure Statement into the file record.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington D.C., 20231 on April 29, 2003.

Ann Marie Cannoni
Registered Representative

Signature

4/29/03
Date

Respectfully submitted

Ann Marie Cannoni
Reg. No. 35,972
Attorney for Applicants
(908) 298-5024

Sheet 1 of 1

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(Use several sheets if necessary)*

| ATTY. DOCKET NO. | SERIAL NO. |
|---|---|
| CV01489K | 10/057,323 |
| APPLICANT: Harry R. Davis, et al. | |
| FILING DATE: January 25, 2002 | GROUP: 1619 |

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

| | | |
|---|---|---|
| | AA | ***Exhibit A:*** SCH 58235 Micronized (ezetimibe), Drug Formulation Development Summary |
| | AB | ***Exhibit B:*** SCH 58235 (ezetimibe), Drug Formulation Development Summary |
| | AC | ***Exhibit C:*** SCH 58235 (ezetimibe), Drug Formulation Development Summary |
| | AD | ***Exhibit D:*** SCH 58235 (ezetimibe), Drug Formulation Development Summary |
| | AE | ***Exhibit E:*** SCH 58235 (ezetimibe), Drug Formulation Development Summary |
| | AF | ***Exhibit F:*** SCH 58235 (ezetimibe), Drug Formulation Development Summary |
| | AG | ***Exhibit G:*** SCH 58235 (ezetimibe), Drug Formulation Development Summary |
| | AH | ***Exhibit H:*** SCH 58235 (ezetimibe), Drug Formulation Development Summary |
| | AI | ***Exhibit 1:*** Master Sheet for the SCH 58235 and Lovastatin Research Study, *Schering-Plough Research Institute* (Protocol No. C906-411), page 1576-1585 |
| | AJ | ***Exhibit 2:*** Medical Research Study #1055/97, SCH 58235: Bioavailability of Single Oral Doses of Two Prototype Tablet Formulations and the Reference Capsule Formulation of SCH 58235 in Normal Male Volunteers: A Four Way Crossover Study #C97-221-01, Informed Consent, *Peninsular Testing Corporation*, page 106-112 |
| | AK | ***Exhibit 3:*** Consent Form to Participate in a Research Study, "A Phase II Double Blind Dose Response Investigation of Efficacy and Safety of Four Doses of SCH 58235 Compared to Placebo in Subjects with Primary Hypercholesterolemia," *Schering-Plough Research Institute* (Protocol No. C98-010), page 1558-1566 |
| | AL | ***Exhibit 4:*** Medical Research Study #1096/99, SCH 58235: Pharmacokinetic Pharmacodynamic Drug Interaction Study with Digoxin in Healthy Volunteers #C98-114, Informed Consent, *Peninsular Testing Corporation*, page 124-130 |
| | AM | ***Exhibit 5:*** Informed Consent, "SCH 58235: Assessment of Multiple-Dose Drug Interaction Between 58235 and Gemfibrozil in Healthy Volunteers," *Schering-Plough Research Institute*, page 1-8 |

| EXAMINER | DATE CONSIDERED |
|---|---|
| | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.